

## REMARKS

Claims 15-21 and 33-36 are pending, and new claims 37-61 have been added. By this amendment, Applicants have canceled claims 1, 9-14, and 22-32 without prejudice or disclaimer. Applicants reserve the right to pursue these canceled claims in a divisional or continuation application(s).

Applicants have amended claim 15 by adding the phrases “for detecting or staging anthrax infection in a vertebrate of interest” and “wherein the level of said soluble poly glutamic acid is indicative of anthrax infection, or stage thereof, in said vertebrate.” This amendment is supported at least by Example 5, Figure 7A, and paragraphs 18-19 and 91-97 of the specification.

Applicants have also amended claim 20 by adding the abbreviation “( $\gamma$ DPGA)” for the term “poly  $\gamma$ -D-glutamic acid.” Applicants respectfully submit that this amendment is purely cosmetic and supported at least by paragraph 9 of the specification.

In addition, applicants have amended claim 21 by adding the phrase “wherein said reference level is an average level of soluble poly glutamic acid in blood samples from humans who have not been infected by *Bacillus anthracis*.” Likewise, Applicants have amended claim 34 by adding the phrase “wherein said reference level is an average level of soluble PGA in blood samples from reference vertebrates.” These amendments are supported at least by original claim 22 and paragraphs 93-94 of the specification.

Applicants have also added new claims 37-61. These claims are supported at least by Example 5, Figure 7A, and paragraphs 18-19 and 91-97 of the specification.

Applicants respectfully submit that the amendments to the claims do not introduce new matter. Accordingly, entry of these amendments is respectfully requested.

## Objections to the Specification

On page 2, the Office Action objects to the specification for certain informalities. During a telephone conference with Applicants’ representative on January 3, 2006, the Examiner withdrew the objection. Applicants appreciate the courtesy extended by the Examiner during the telephone conference and his decision to withdraw the objection.

**Claim Rejections Under 35 U.S.C. § 112, Second Paragraph**

On pages 3-4, the Office Action rejects claims 9 and 15-22 under 35 U.S.C. § 112, second paragraph, as being indefinite or lack of antecedent basis. Applicants respectfully traverse the rejection.

Applicants have canceled claims 9 and 22 without prejudice or disclaimer, thereby rendering the rejection of these claims moot.

Applicants have amended claim 15 by reciting “for detecting or staging anthrax infection in a vertebrate of interest” and “wherein the level of said soluble poly glutamic acid is indicative of anthrax infection, or stage thereof, in said vertebrate.” Applicants have also amended claim 21 by reciting “wherein said reference level is an average level of soluble poly glutamic acid in blood samples from humans who have not been infected by *Bacillus anthracis*.” Applicants respectfully submit that these amendments overcome the Examiner’s rejection of claims 15 and 21. Reconsideration and withdrawal of the § 112 rejection of these claims are therefore respectfully requested.

Because claims 16-20 depend from claim 15, Applicants respectfully submit that these claims are also definite. Reconsideration and withdrawal of the § 112 rejection of these claims are respectfully requested.

Applicants have also amended claim 34 by reciting “wherein said reference level is an average level of soluble PGA in blood samples from reference vertebrates.” Applicants believe that this amendment addresses the Examiner’s concern for the term “reference level.”

**Claim Rejections Under 35 U.S.C. § 112, First Paragraph**

On pages 4-5, the Office Action rejects claims 33-36 under 35 U.S.C. § 112, first paragraph, as not being enabled. In particular, the Office Action contends that the specification does not provide enablement for detecting or staging anthrax infection in light of Example 7. Applicants respectfully traverse the rejection.

Applicants respectfully submit that Example 7 does not negate the enablement of claims 33-36. Example 7 does not teach that soluble PGA exists in normal adults who have high levels of anti- $\gamma$ DPGA antibodies. Nor does Schneerson *et al.*, PNAS, 100:8945-8950 (2003), teach that soluble PGA exists in blood or other tissues of *Bacillus*-infected individuals. In fact, Schneerson

*et al.* describes that un-conjugated  $\gamma$ DPGA elicits only “trace levels of antibodies” after multiple rounds of immunization. See Table 1 and left column on page 8948. Therefore, in view of Schneerson *et al.*, one of ordinary skill in the art would not believe that individuals who have high levels of anti- $\gamma$ DPGA necessarily have detectable soluble PGA in their blood or other tissues.

Notwithstanding the poor immunogenicity of  $\gamma$ DPGA, Applicants discovered that anthrax infection can produce a significant amount of soluble PGA in the body fluid of infected individuals, and that the amount of the soluble PGA is statistically significantly correlated with bacteremia in the infected individuals. See Example 5 of the present application. As a result, the present application contemplates the use of soluble PGA as an indicator for the infection or progression of anthrax.

Based on the foregoing, Applicants respectfully submit that the existence of anti- $\gamma$ DGA antibodies in some normal adults do not negate the use of soluble PGA as a marker for anthrax infection or progression. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the enablement rejection of claims 33-36.

#### **Claim Rejections Under 35 U.S.C. § 102**

On page 5, the Office Action rejects claims 9, 15, 16, and 18 under 35 U.S.C. § 102(b) as being anticipated by Froman *et al.*, JOURNAL OF REPRODUCTION AND FERTILITY, 88:405-410 (1990). Applicants respectfully traverse the rejection.

Applicants have canceled claim 9 without prejudice or disclaimer, thereby rendering the rejection of claim 9 moot.

Applicants have also amended claim 15 to recite “wherein the level of said soluble poly glutamic acid is indicative of anthrax infection, or stage thereof, in said vertebrate.” Applicants respectfully submit that this amendment obviates the Examiner’s § 102(b) rejection of claim 15.

Because claims 16 and 18 depend from claim 15, Applicants respectfully submit that claims 16 and 18 are also patentable over Froman *et al.*

Based on all of the above reasons, Applicants respectfully request the Examiner to reconsider and withdraw the § 102 rejection of claims 9, 15, 16, and 18.

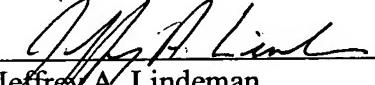
**Conclusion**

For at least the reasons set forth above, Applicants respectfully submit that this application is in condition for allowance. Favorable consideration and prompt allowance of the claims are earnestly solicited. Although Applicants believe that no fee is due for the instant response, the Commissioner is hereby authorized to charge any payment deficiency to deposit account number 19-2380 referring to attorney docket number 031673-003000.

Should the Examiner have any questions, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,

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